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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,619	02/20/2004	Ming Chiu Fung	14761US02	7207
40614 7590 01/23/2007 WILKINSON & GRIST 6TH FLOOR, PRINCE'S BUILDING CHATER ROAD, CENTRAL HONG KONG, CHINA			EXAMINER MI, QIUWEN	
			ART UNIT 1655	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/23/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/783,619

Applicant(s)

FUNG ET AL.

Examiner

Qiuwen Mi

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 60-71 is/are pending in the application.
- 4a) Of the above claim(s) 70 and 71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 60-69 is/are rejected.
- 7) ☒ Claim(s) 60-69 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Election/Restrictions**

Applicant's election of claims 60-69 in the reply filed on 12/7/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 70 and 71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected claims.

### **Claim Objections**

Claims 60-69 are objected to because of the following informalities: "hemoglobinopahthies" should be spelled as "hemoglobinopathies". Appropriate correction is required.

### **Claim Rejections –35 USC § 112, 1st**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 60-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Pathological condition associated with hemoglobinopathies cannot be prevented. It can be treated, but not prevented. There is no evidence that one would not ever get pathological condition associated with hemoglobinopathies by consuming the claimed *Trichosanthes* extract. Unless Applicant can show on the record that diabetes would be completely prevented in every instance, Applicant is requested to cancel this claim.

### **Claim Rejections –35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 60-69 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either an asserted utility or a well established utility. The claims recite preventing a pathological condition associated with hemoglobinopathies in a mammal. The broadest reasonable interpretation of the term pathological condition merely requires that one mammal gets sick. There is no evidence that pathological condition would be prevented, therefore the utility would not be credible.

**Claim Rejections –35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 60-69 are rejected under 35 USC § 102 (b) as being anticipated by Ozaki et al (Biological & pharmaceutical bulletin, (1996 Aug) Vol. 19, No. 8, pp. 1046-8).

Ozaki et al teach the anti-inflammatory effect of 50% ethanol (polarity index 5.2) extract obtained from the fruit of *Trichosanthes kirilowii* (see the Abstract).

Claims 60-69 are rejected under 35 USC § 102 (b) as being anticipated by Kwak et al (US 5, 910, 307).

Kwak et al teach a process for manufacturing a combined herbal preparations comprising *Trichosanthes* root extracted with water or alcoholic solution. Kwak et al also indicate that resulting mixture is re-extracted with water or alcoholic solution under reflux and filtered. The filtrate is brought up with previously prepared solution and filtered. The alcohol layer is concentrated under reduced pressure at 60-70°C. The final extract is hydrolyzed, sufficient amount of oleanolic acid are present as sapogenin (see the entire document, e.g., column 3, lines 5-10, 25-40; column 5, lines 20-25).

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Claims 60-69 are rejected under 35 USC § 102 (b) as being anticipated by Lee et al (KR 2001106527).

Lee et al teach a whitening cosmetic composition comprising *Trichosanthes kirilowii* extracted with an ethanol aqueous solution and filtered (see the Abstract).

The intended use and functional language in Claims 60-69 are given no patentable weight since they do not further limit the composition. Because they recite intended use of the composition and since this is not a method of use, it does not matter what the composition is used for. Unless the Applicant could provide evidence that functional language in the claims would render the *Trichosanthes* extract materially different than the extracts in the references, the references are deemed to anticipate the instant claims above.

### **Claim Rejections –35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 60-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwak et al (US 5, 910, 307) in view of Ozaki et al (Biological & pharmaceutical bulletin, (1996 Aug) Vol. 19, No. 8, pp. 1046-8).

Kwak et al teach a process for manufacturing a combined herbal preparations comprising *Trichosanthes* root extracted with water or alcoholic solution. Kwak et al also indicate that resulting mixture is re-extracted with water or alcoholic solution under reflux and filtered. The filtrate is brought up with previously prepared solution and filtered. The alcohol layer is concentrated under reduced pressure at 60-70°C. The final extract is hydrolyzed, sufficient amount of oleanolic acid are present as sapogenin (see the entire document, e.g., column 3, lines 5-10, 25-40; column 5, lines 20-25).

Kwak et al do not teach using ethanol to extract *Trichosanthes*.

Ozaki et al teach the anti-inflammatory effect of 50% ethanol (polarity index 5.2) extract obtained from the fruit of *Trichosanthes kirilowii* (see the Abstract)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to extract *Trichosanthes* with ethanol since Ozaki et al teach using 50% ethanol to extract *Trichosanthes* and the extract shows antiinflammatory and analgesic activities, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate concentration of ethanol to further purify the *Trichosanthes* extract) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

### Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry Mckelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MICHAEL MELLER  
PRIMARY EXAMINER